



Commentary on COVID-19 Clinical Trials in India Based on CTRI (Clinical Trials Registry-India)

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STUDY DESCRIPTION

Convergent effect of multiple efforts made by Indian scientist and physicians to find effective drugs for Covid-19 is reflected in CTRI (Clinical Trials Registry- India) [1]. Allopathic and AYUSH systems share the total number of registered Clinical trials (n=233 as on from 1st March 2020 to 22nd June 2020). Out of these, 146 were Interventional trials, 84 Observational trials, and three Post-marketing surveillance. In most of the trials, the interventional agent is either multiple drug combinations or compound drug formulations compared to single drug administration. Among the trials, 46 Allopathic interventions, 41 Ayurveda interventions, 14 Homeopathy interventions, 11 Siddha Interventions, one in Unani, and 2 in yoga and Naturopathy.

Preparedness of various Indian health stakeholders controlled by two Ministries, one dealing with the conventional therapy (Ministry of Health and Family welfare) and the other with Indian traditional medicine (Ministry of AYUSH) could be tracked from CTRI. Clinical trial registries also reported newer ideas and newer interventions. The kinesis of conducting a Clinical trial during a pandemic is different from the normal situation affirmed by MEURI guidelines [2,3]. The decision of Govt. of India to register every clinical trial in CTRI has created accountability and responsibility during pandemics. Ministry of AYUSH has released a particular GO, regulating the clinical trial during COVID -19 [4].

Randomized, non-randomized, observational studies, including Questionnaire, were the frequent Study designs. Global trials were very minimal, indicating distancing also in research. This pandemic has raised traditional medicine status in the country, which is evident from equal sharing of the total registered clinical trials. This may also be a reason for lesser mortality in a thickly populated country [5,6]

Allopathy and AYUSH's health sectors have attempted rapidity, which shows their surge in acting against COVID -19. Revalidated interventions that have been used earlier in Dengue, Malaria, Immunomodulators and Earlier anti-virals and drugs used in Cancer and HIV are among the selected repurposed interventions.

Prophylactic interventions equate therapeutic studies, and AYUSH interventions have a major role. Integrative clinical studies are higher in number during Covid-19. Therapeutic exploratory and therapeutic confirmatory precedes safety trials; however, some studies using a repurposing technique checked the effects of the lozenges available in the market. Even though there are quite a few blinded studies (Double, triple, quadruple), the blinding tendency is minimal (14%) due to non-conformity in therapeutic interventions. However, research institutions and medical colleges allowed the country to make effective participation. In a particular time, sub-continent had 107 trials more than China, the epicentre of Covid -19 [7]. The outcome objectives were symptom reduction, getting negative in RT-PCR, reduction in hospitalization, minimal use of ICU, ventilators, and reduced mortality were the objectives observed. Post COVID-19 management clinical trials were not registered during the said time. However, there exists a lot of scope and necessity to do trials in Post Covid prospectively. These clinical trials confirm the preparedness of the subcontinent in pandemic mitigation.

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